

K 011147

(Per 21 CFR § 801.109)

510(k) SUMMARY

FEB 15 2002

I. General Information on Submitter:

Name: CAVITAT Medical Technologies, Inc.
10691 E. Bethany Drive, Suite 900
Aurora, Colorado 80014
Tele: (303) 755-2688
Fax: (303) 755-2699

II. General Information on Device

Name: CAVITAT™ (Ultrasonograph)

Classification Name: Extraoral Source X-Ray System

III. Predicate Devices:

Existing extraoral X-ray devices and
MYSONO 201 Diagnostic Ultrasound System and Transducers (K003121)

IV. Description of the Device:

The CAVITAT™ (Ultrasonograph) CAV 40000-1 or CAV 40000-3 with WIN/CAV Software (Release 1.05) consists of a transmitter, pulsing transducer, receiver, and a dedicated computer using an AMD processor. The computer system includes a LCD monitor, a color inkjet printer, and patented circuitry installed by CAVITAT Medical Technologies, the manufacturer of the device. The transmitter sends an electrical signal to the transducer which converts it into a pulsed ultrasonic sound wave that is transmitted at a rate of 27,000 sound pulses per microsecond, clocked at 2.5 megahertz at 1,042 feet per second at 98°F. These ultrasonic pulses travel through alveolar bone, and are received by the receiver membrane, which converts it into an electrical signal. It is this electrical signal that is displayed on the computer monitor. The display represents an average of two to eight pulses received when the button/foot pedal is pushed. The frequency used by the CAVITAT™ (Ultrasonograph) does not record the presence of soft tissue. It is the lack of interconnectivity and thickness of trabeculae that determines signal strength, and therefore the height of the three-dimensional column display. The colors of the columns displayed are non-linear.

V. Intended Use:

The CAVITAT™ (Ultrasonograph) CAV 40000-1 or CAV 40000-3 with WIN/CAV Software (Release 1.05) provides an ultrasound-based, three-dimensional image of the alveolar process of the maxilla and mandible as an adjunct to standard radiographic evaluation and clinical diagnostic procedures.

The clinical significance and correlation of the CAVITAT™ (Ultrasonograph) images, including column height and color grading, has not been established for specific osseous pathology, or normal bone. Positive images represent alveolar regions that attenuate ultrasound signals.

VI. Technological Characteristics of Device Compared to Predicate Devices:

The technological characteristics of the CAVITAT™ (Ultrasonograph) are identical to those of a diagnostic pulse-echo ultrasound device, with the exception of the fact that the CAVITAT™ (Ultrasonograph) measures the signal that passes through the bone rather than the return or echo signal. Positive images represent alveolar regions that attenuate ultrasound signals.

VII. Summary of Safety and Effectiveness Data

The CAVITAT™ (Ultrasonograph) was tested for acoustic output in accordance with FDA requirements for diagnostic ultrasound to confirm the safety of the device. The device met or exceeded all applicable FDA requirements. The effectiveness of the CAVITAT™ (Ultrasonograph) was demonstrated by a clinical study in which both radiographs and ultrasound-based, three-dimensional images of 92 alveolar sites were compared and confirmed with histopathologic examination. The results from the clinical study confirmed that the device is effective as an adjunct to standard radiographic evaluation and clinical diagnostic procedures.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 15 2002

Cavitat Medical Technologies, Inc.
C/O Mr. Larry R. Pilot
Mckenna and Cuneo, L.L.P.
1900 K Street, N. W.
Washington, D.C. 20006-1108

Re: K011147

Trade/Device Name: Cavitat™ (Ultrasonograph), CAV 40000-1 and CAV
40000-3 with WIN/CAV Software (Release 1.05)
Regulation Number: 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: II
Product Code: EHD
Dated: January 14, 2002
Received: January 14, 2002

Dear Mr. Pilot :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

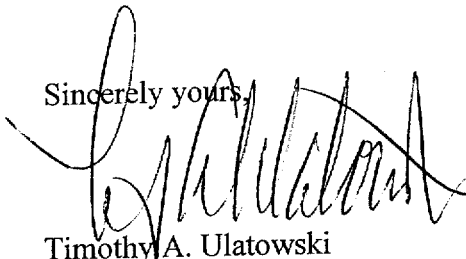
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski
Director

Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

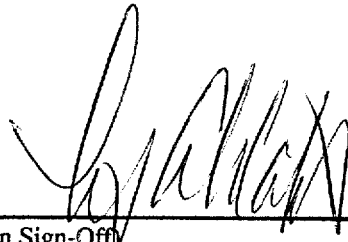
510(k) Number:

Device Name: CAVITAT™ (Ultrasonograph)

Indications for Use:

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(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number

K011147

PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒

OR

Over-The-Counter Use ☐